

Remarks

Claims 1, 2, 6 to 9 and 11 to 16 and 18 to 21 are pending in this application of which claims 1, 2 and 18 are in independent form. New claims 18 to 21 are based on claims 11 to 14.

Allowable Subject Matter

Applicant would like to thank the Office for acknowledging the allowability of claim 1.

35 USC §112, second paragraph rejection

On pages 2 of the Action, the Office continued to reject claims 2, 6 to 9, 15 and 16 under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office rejected in particular the formula shown in claim 2, which indicated no charge, while the definition of X_1 and X_2 renders clear that also charged compounds are included.

The Office expressed the opinion that the formula as shown thus runs contrary to standard nomenclature in the art.

In response, applicant has amended the claim to show the formula not only without charge, but also charged. The cationic charge under (II) represents, e.g., X_1, X_2 = calcium, magnesium, while the anionic charge under (III) takes into account the possibility of a negatively charged aryl residue as X_1, X_2 .

Applicant submits that claim 2 now readily meets the threshold requirement of clarity and particularity.

35 USC §112, first paragraph rejection

On page 3 of the Action, the Office rejected claims 11 to 14 as non-enabled under 35 USC §112, first paragraph.

While the Office withdrew the rejection with regard to treatment, the Office found applicant's argument with regard to prophylaxis non-persuasive. The treatment aspect of claims 11 to 14 is
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now represented by new claims 18 to 21. Claims 11 to 14 focus on prophylaxis.

Applicant previously argued that a person skilled in the art, e.g., a medical scientist or a physician, would know how to administer the medicament for prophylaxis, e.g., based on the medical history of the patient and his/her family.

The Office disagreed based on several articles. The Office noted that Basler and Groettrup, *Drug Aging*, Vol 24, no. 3, p. 197-221 (2007), concluded that in the case of prostate cancer, especially metastatic prostate cancer, the development of new breakthrough treatment options in tumor vaccination have not been achieved. The Office noted that none of the current treatments prevent (prophylaxis) metastatic prostate cancer. Citing Shore et al., *Aliment Pharmacol Ther*, Vol. 18, pp. 1049-1069 (2003), the Office stated that the only treatment that cures pancreatic cancer is surgery. The Office cited Boulikas et al., *Oncology Reports*, Vol. 10, pp 1663-1682 (2003) as a review of the last 20 years of platinum drugs for the use in cancer treatment. Since the article only mentions the use of these platinum compounds as treatment of cancer and not as a preventive drug, the Office concluded that it is clear that at the present time none of the platinum drugs available are use in the prevention (or prophylaxis) of cancer. Further, the Office stated that all of the platinum complexes used as anti-cancer drugs are not viewed as part of the strategies currently in development in the area of tumor vaccination. The Office expressed the opinion that one skilled in the art will, presented with the above, logically conclude that platinum drugs are well suited for treatment of cancer but that there is no evidence that such drugs can be use for the prevention of cancer. Therefore, the Office concluded one skilled in the art would not be able, without undue experimentation to practice the claimed invention.

Applicant notes that the articles cited by the Office refer to a number of specific cases, which can, however, not be readily generalized. With regard to Baseler and Groettrup, applicant notes that this article is focused on prostate cancer and does not mention oxoplatin and as such provides little insight with regard to any prophylactic use of oxoplatin. Also, vaccination is only a special case of prophylactic treatment. In prophylaxis a regular intake of medicaments can prevent development of a clinical pattern.

This does not necessary need to happen by the activation of the body's own immune defense (which is the case in vaccination).

The fact that the prior art described specific cases in which prophylaxis proved impossible, does not mean that the person skilled in the art does not know how to employ a new medicament for prophylactic use. There is a considerable number of diseases in which the same medicament is administered, even at the same dosing, for prophylaxis and therapy. Examples include antibiotics for different bacterial infections, MALARONE for malaria infections or blood thinners for different pain indications.

The person skilled in the art is also able to adjust the dosing as far as necessary through routine experimentation.

Cancers involve a complex clinical picture and the course of the disease varies widely from patient to patient. As a result, physicians are used to adjust the treatment, including dosing, intervals and mode of administration as well as length of use, to the individual patient. Age, weight, gender, type of cancer, progression of the disease, disease history and responses to past treatments are of relevance. In the treatment of serious illnesses it is in fact rather uncommon that a standard therapy is administered without individual adjustments. Also, for the prophylactic treatment, the administration may need to be adjusted individually, which is well within the abilities of the person of skilled in the art. In the prophylactic administration of oxoplatin and its derivatives the same factors are to be considered as in therapy. Important are also genetic predisposition and family disease history.

There are a number of clinical trials for different applications of chemoprophylaxis for cancers. The fact that some of the trials were not successful does not mean that chemoprophylaxis is not possible or that undue experimentation would be required by a person skilled in the art to administer a medicament prophylactically. As outlined above, many medicaments have a proven track record in prophylaxis. Considering the level of the person of ordinary skill in the art, the quantity of experimentation needed to make or use the invention based on the content of the disclosure, is not undue. The Office is also directed to the specification at page 10, the paragraph starting on line 30; page 16, starting on line 9; page 22, the paragraph starting on line 19 and page 23, the paragraph starting on line 25.

The undersigned urges the Office to call her at the number provided below so that any issues or concerns can be promptly addressed and/or clarified. Otherwise, an early notice of allowance is respectfully requested.

No fees in addition to those submitted herewith are believed to be due. However, the Commissioner is authorized to charge undersign's deposit account for any fees that may be required in connection with this filing.

Respectfully submitted,

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